CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 12 **Date: April 30, 2004**

CHANGE REQUEST 3290

I. SUMMARY OF CHANGES: Following an internal reconsideration review of Cardiac Pacemakers, CMS is making minor revisions to the text to transfer the focus of the NCD from the actual pacemaker implantation procedure itself to the reasonable and necessary medical indications that justify cardiac pacing. Therefore, only the framework of the NCD is revised and not the NCD itself.

NEW/REVISED MATERIAL - EFFECTIVE DATE: April 30, 2004
***IMPLEMENTATION DATE: April 30, 2004**

(This revision to §20.8 of Pub. 100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/Table of Contents
R	1/20.8 Cardiac Pacemakers

***III. FUNDING:**
These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

20.8 - Cardiac Pacemakers (Effective April 30, 2004)

(Rev.12, 4-30-04)

Cardiac pacemakers are self-contained, battery-operated units that send electrical stimulation to the heart. They are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate and/or rhythm. Pacemakers are generally used for persistent, symptomatic second- or third-degree atrioventricular (AV) block and symptomatic sinus bradycardia.

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the following conditions and limitations. While cardiac pacemakers have been covered under Medicare for many years, there were no specific guidelines for their ***use*** other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for ***cardiac pacing*** on or after the effective dates of this instruction are subject to these guidelines, which are based on certain assumptions regarding the clinical goals of ***cardiac pacing***. While some uses of pacemakers are relatively certain or unambiguous, many other uses require considerable expertise and judgment.

Consequently, the medical necessity for ***permanent cardiac pacing*** must be viewed in the context of overall patient management. The appropriateness of such ***pacing*** may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemaker ***use*** are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which ***permanent cardiac pacing*** may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of ***new uses*** for ***cardiac pacing*** in ***new classes of patients*** may change as more ***more conclusive evidence*** becomes available. This instruction applies only to permanent ***cardiac*** pacemakers, and does not address the use of temporary, non-implanted pacemakers.

The two groups of conditions outlined below deal with the necessity for ***cardiac pacing*** for patients in general. These are intended as guidelines in assessing the medical necessity for ***pacing therapies, taking into*** account the ***particular*** circumstances ***in each case***. However, as a general rule, the two groups of current medical concepts ***may be viewed*** as representing:

Group I: Single-Chamber Cardiac Pacemakers – a) conditions under which single chamber pacemaker claims may be considered covered without further claims development; and b) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances exist of the sufficiency to convince the contractor that the claim should be paid.

Group II: Dual-Chamber Cardiac Pacemakers - a) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and b) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single- and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the contractor that the claim should be paid.

CMS opened the NCD on Cardiac Pacemakers to afford the public an opportunity to comment on the proposal to revise the language contained in the instruction. The revisions transfer the focus of the NCD from the actual pacemaker implantation

procedure itself to the reasonable and necessary medical indications that justify cardiac pacing. This is consistent with our findings that pacemaker implantation is no longer considered routinely harmful or an experimental procedure.

Group I: Single-Chamber Cardiac Pacemakers ***(Effective March 16, 1983)***

A. Nationally Covered Indications

Conditions under which ***cardiac pacing*** is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third-degree) AV heart block.

2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.

3. Second-degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat. ***P-R interval indicates the time taken for an impulse to travel from the atria to the ventricles on an electrocardiogram).***

4. Second-degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.

5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

7. Sinus bradycardia is the consequence of long-term necessary drug treatment for which there is no acceptable alternative when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block (i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest) when accompanied by significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high-degree AV block which is

unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, congestive heart failure, dizziness or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.

13. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third-degree) and/or Mobitz Type II second-degree AV block in association with bundle branch block.

14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

(Effective May 9, 1985)

15. Second-degree AV heart block of Type I with the QRS complexes prolonged.

B. Nationally Noncovered Indications

Conditions which, although used by some physicians as ***a*** basis for ***permanent cardiac pacing***, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of ***the above indications***. Contractors should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim, ***since additional claims development may be required.*** The object of such further development is to establish whether the particular claim actually meets the conditions in a) above. In claims where this is not the case or where such an event appears unlikely, the contractor may deny the claim

1. Syncope of undetermined cause.

2. Sinus bradycardia without significant symptoms.

3. Sino-atrial block or sinus arrest without significant symptoms.

4. Prolonged ***P-***R intervals with atrial fibrillation (without third-degree AV block) or with other causes of transient ventricular pause.

5. Bradycardia during sleep.

6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block).

7. Asymptomatic second-degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His bundle ***(a component of the electrical conduction system of the heart)***.

Effective October 1, 2001

8. Asymptomatic bradycardia in post-mycardial infarction patients about to initiate long-term beta-blocker drug therapy.

Group II: Dual-Chamber Cardiac Pacemakers – ***(Effective May 9, 1985)***

A. Nationally Covered Indications

Conditions under dual-chamber ***cardiac pacing*** are considered acceptable or necessary in the general medical community unless conditions 1 and 2 ***under*** Group II. B., are present:

1. Patients in who single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.

2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.

3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with congestive heart failure despite adequate other medical measures.

4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the conditions, as listed in Group I. A., if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. Nationally Noncovered Indications

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium.

2. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia.

3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

4. Prophylactic pacemaker use following recovery from acute myocardial infarction during which there was temporary complete (third-degree) and/or Type II second-degree AV block in association with bundle branch block.

C. Other

All other indications for cardiac pacing for which CMS has not specifically indicated coverage remain nationally noncovered.

(This NCD last reviewed April 2004.)